DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
Seattle District
Pacific Region
22201 23rd Drive SE
Bothell, WA 98021-4421

Telephone: 425-486-8788
FAX: 425-483-4996

August 18, 2000

VIA FEDERAL EXPRESS

In reply refer to Warning Letter SEA 00-86

Roger D. May, Owner
Lisa J. May, Owner
Smoki Foods, Inc.
19002 13th Place South, Building 3
Seattle, Washington 98148

WARNING LETTER

Dear Mr. and Mrs. May:

We inspected your firm located at 19002 13th Place South, Building 3, Seattle, Washington, on July 18, 2000, and found that you have serious deviations from Title 21 of the Code of Federal Regulations (21 CFR) Part 123 - Fish and Fishery Products (Seafood HACCP regulations). An FDA 483 form (copy enclosed) listing the deviations was presented to Mr. May at the conclusion of the inspection. These deviations, some of which were previously brought to your attention, cause your air packed hot and cold smoked salmon to be in violation of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). You can find this Act and the Seafood HACCP regulations through links in FDA's homepage at www.fda.gov.

The deviations were as follows:

1. You must have a HACCP plan to control any food safety hazards that are reasonably likely to occur, to comply with 21 CFR 123.6(b). Your firm does not have a HACCP plan for your hot and cold smoked salmon, air packed in bulk boxes, intended to be refrigerated, to control the food safety hazard of *Clostridium botulinum* growth and toxin formation.

   This deficiency was brought to your attention during the January 14, 19, and 20, 2000 inspection and presented to you on the form FDA 483, Inspectional Observations.

2. You must have sanitation control records that document monitoring and corrections, to comply with 21 CFR 123.11(c). Your firm's sanitation monitoring records do not include prevention of cross contamination.

This letter may not list all the deviations at your facility. You are responsible for ensuring your processing plant operates in compliance with the Act, the Seafood HACCP regulations and the Good Manufacturing Practice regulations (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the Federal Food, Drug, and Cosmetic Act and all applicable regulations.

We may take further action if you do not promptly correct these violations. Currently, you are under a Consent Decree of Permanent Injunction, C00-1076, signed on July 10, 2000, and are enjoined under the provisions of 21 U.S.C. 332(a) from processing, preparing, packing, holding and distributing, any vacuum-packaged smoked fishery product, unless and until you comply with the terms outlined in the decree.

Please respond in writing within three (3) weeks from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You may wish to include in your response documentation your revised HACCP plan and copies of your monitoring records or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations.

Please send your reply to the Food and Drug Administration, Attention: Lisa M. Elrand, Compliance Officer, 22201 23rd Drive SE, Bothell, Washington 98021. If you have questions regarding any issue in this letter, please contact Lisa M. Elrand, Compliance Officer at (425) 483-4913.

Sincerely,

Charles M. Breen
District Director

Enclosures:
Form FDA 483
21 CFR PART 123
Section 402 of the Federal Food, Drug, and Cosmetic Act

cc: WSDA with disclosure statement